

Applicant(s): Bonutti, Peter M
Application No.: 09/728,553
Examiner: A Lewis

Remarks

Claims 100-106, 169-175, 177-194, 199-217, and 223-242 are pending in the application and are presented for the Examiner's review and consideration. Claims 100, 105, 169, 171, 177-179, 200, 201, 205, 208-210, 225, 231, 232, and 242 have been amended and claims 1-99, 107-168, 176, 195-198, and 218-222 have been cancelled. Applicant believes the claim amendments, cancellations, and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Applicant appreciates the courtesies extending to Mr. Seth Blum during the telephone interview conducted January 26, 2004 to determine the status of claims 116-138, which were inadvertently omitted from the Restriction Requirement and the first Office Action. As indicated in the Interview Summary mailed January 28, 2004, claims 116-138 fell within Group I of the Restriction Requirement. Accordingly, Applicant respectfully submits that the Interview Summary accurately reflects the substance of the interview.

Allowable Subject Matter

Applicant acknowledges with appreciation the allowance of claims 181-194, 213-217, 223, and 224. The Examiner also indicated that claims 171-177, 179, 180, 200, 201, 205, 207, 209, 210, 212, 231, 232, and 235-242 would be allowable if rewritten in independent form.

Applicant has rewritten claims 171, 177-179, 200, 201, 205, 209, 210, 231, 232, and 242 as required by the Examiner. Accordingly, Applicant respectfully submits that these claims are in condition for allowance. Furthermore, as claims 172-175 depend from claim 171 and claim 180 depends from claim 179, Applicant also submits that these dependent claims are also in condition for allowance.

Although Applicant disagrees with the rejection of independent claim 169, Applicant has rewritten claim 169 to include all the elements of allowable claim 176, which has been canceled. In light of the foregoing, independent claim 169 is respectfully submitted to be allowable. As claim 170 depends from claim 169 and necessarily include all the elements of its base claim, it is

Applicant(s): Bonutti, Peter M
Application No.: 09/728,553
Examiner: A Lewis

respectfully submitted that claim 170 is patentable as well.

35 U.S.C. § 102(b)-Anderson.

Claims 100-106 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,244,362 to Anderson. ("Anderson"). The Examiner asserted:

As to claim 100, Anderson discloses a method of treating a patient, said method comprising moving a leading end portion (27) of a member (23) disposed in a patient's body (fig. 5) relative to body tissue, said step of moving a leading end portion of a member relative to body tissue includes attracting the leading end portion of the member with a magnetic field (41) emanating from a location outside of the patient's body (fig. 5).

For the reasons set forth below, Applicant respectfully submits that claims 100-106 are not taught or suggested by Anderson.

Anderson discloses a magnetically controllable stylet for assisting in the insertion of an endotracheal tube. (Col. 1, lns. 5-7). Anderson provides a stylet 23 and an exterior magnet 44. (Col. 5, lns. 63-65). The magnet 41 is preferably a housing of plastic material 43 having a magnet secured therein with one end having a concave face. (Col 5, lns. 66-68). The main body 25 of the stylet is comprised of coiled spring of a non-magnetic material (Col 6, lns. 5-6). A magnet 27 is secured to the other end of the spring. (Col 6, lns. 10-11).

The stylet 23 is inserted with the magnetic end entering into the throat of the patient. (Col. 6, lns. 28-30 and FIG. 5). The magnet 41 is placed exteriorly in the midline adjacent to the prominence of the thyroid cartilage, or "Adam's apple." (Col. 6, lns. 34-36). This is easily distinguishable on the patient and places the magnet in a proper spot for attracting the attracting the magnetized end of the stylet into the tracheal passage. (Col. 6, lines 36-39). The stylet is then inserted into the tracheal cavity by sliding it along inside the endotracheal tube. (Col. 6, lines 40-42 and FIG. 6).

Accordingly, Anderson discloses a stylet for assisting with the insertion of an endotracheal tube. The stylet includes a permanent magnet at its end, which is inserted into the

Applicant(s): Bonutti, Peter M
Application No.: 09/728,553
Examiner: A Lewis

throat of a patient. A second, external, permanent magnet is positioned adjacent to the Adam's apple of the patient to draw the end of the stylet into the tracheal passage. As disclosed, both the magnets are permanent, having fixed magnetic field strengths.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831 (Fed. Cir. 1990). MPEP § 2131 (Eighth Edition, rev February 2003).

Claim 100 recites a method for treating a patient. The method includes moving a leading end portion of a member disposed in a patient's body relative to body tissue. The movement of the leading end portion of the member is facilitated by attracting the leading end portion of the member with a magnetic field emanating from a location outside of the patient's body. During movement of the leading end portion of the member the magnetic field strength is controlled.

Applicant submits that the invention as claimed in claim 100 is not disclosed in Anderson. Specifically, Anderson discloses a stylet with a permanent magnet at its end, which is inserted into the throat of a patient, and a second, external, permanent magnet, positioned adjacent to the Adam's apple of the patient, to draw the end of the stylet into the tracheal passage. As the magnets are permanent they each have fixed magnetic field strengths. Accordingly, Anderson does not disclose all of the elements of claim 100.

In light of the foregoing, independent claim 100 is respectfully submitted to be patentable over Anderson. As claims 101-104 depend from amended claim 100 and necessarily include all the elements of their base claim, Applicant hereby respectfully requests reconsideration and withdrawal of the §102(b) rejections.

Claim 105 was also rejected as being anticipated by Anderson. Similar to claim 100, claim 105 now recites "controlling the magnetic field strength while moving the leading end portion of the member." At least for the same reasons as set forth above, Applicant submits

Applicant(s): Bonutti, Peter M
Application No.: 09/728,553
Examiner: A Lewis

Applicant submits that the invention as claimed in claim 105 is not taught or suggested by Anderson.

In light of the foregoing, independent claim 105 is respectfully submitted to be patentable over Anderson. As claim 106 depends from amended claim 105 and necessarily include all the elements of the base claim, Applicant hereby respectfully requests reconsideration and withdrawal of the §102(b) rejections.

35 U.S.C. § 102(b)-White

Claims 169, 170, 178, 202-204, 208, and 211 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,257,636 to White ("White").

As an initial matter, Applicant respectfully submits that the rejection of claims 169, 170, and 178 is moot as discussed above.

With respect to claim 202, the Examiner asserted:

White discloses an apparatus for use in tracheal intubation of a patient, said apparatus comprising a tracheal tube which is movable along an insertion path into a patient's trachea, an emitter (20) which provides an output, and a detector (22) which responds to the output from said emitter, a first one of said emitter (20) and said detector being connected with said tracheal tube (#18 of Fig. 7) for movement therewith along the inserting path, a second one of said emitter and said detector (22) being disposed adjacent to an outer surface of the patient's neck (fig. 11, 14-18) during movement of said tracheal tube along the insertion.

For the reasons set forth below, Applicant respectfully submits that claims 202-204 are not taught or suggested by White.

White discloses an apparatus for determining the optimum position of an endotracheal tube. (Col. 3, Ins. 19-21). Apparatus 10 is preferably comprised of an adaptor 14, a stylet 16, which is adjustably and removably attached to adaptor 14, an endotracheal tube 18, a means for producing magnetic flux 20, and a means for sensing magnetic flux 22. (Col. 4, lines 10-13). A magnetic sensing means 22 is preferably comprised of a body 30, an indicator 32, and a means for

Applicant(s): Bonutti, Peter M
Application No.: 09/728,553
Examiner: A Lewis

removably attaching sensing means 22 to a patient's neck. (Col. 4, lns. 31-34). Sensor 22 is preferably attached to the suprasternal notch 90 of the patient. (Col. 8, lns. 27-28). The proximal end 60 of the stylet 16 of this invention is attached to a means 20 for producing magnetic flux. (Col. 6, lns. 30-31).

As such, White discloses a stylet having a means for producing a magnetic flux at its proximal end. The stylet is inserted into the patient, where an external magnetic flux detector attached the suprasternal notch sensing the magnetic flux. White does not disclose a magnetic flux detector on the stylet nor a mean for producing magnetic flux external to the patient, i.e., on the suprasternal notch of the patient.

Claim 202 recites an apparatus for use in tracheal intubation of a patient. The apparatus includes a tracheal tube which is moveable along an insertion path into a patient's trachea. An emitter that provides an output, and a detector that responds to the output from said emitter are also provided. A first one of the emitter and the detector is connected with said tracheal tube for movement therewith along the inserting path. A second one of the emitter and the detector is disposed adjacent to an outer surface of the patient's neck during movement of said tracheal tube along the insertion path.

Applicant submits that the invention as claimed in claim 202 is not taught or suggested by White. Specifically, White discloses a stylet having a means for producing a magnetic flux at its proximal end, wherein the proximal end of the stylet is inserted into the patient, and an external magnetic flux detector, attached the suprasternal notch, for sensing the magnetic flux. Only an internal means for producing a magnetic flux and an external magnetic flux detector are disclosed. As such, White does not disclose all of the elements of claim 202.

In light of the foregoing, independent claim 202 is respectfully submitted to be patentable over White. As claims 203 and 204 depend from claim 202 and necessarily include all the elements of their base claim, Applicant hereby respectfully requests reconsideration and withdrawal of the §102(b) rejection.

Claims 208 and 211 were rejected as being anticipated by White. The Examiner asserted:

Applicant(s): Bonutti, Peter M
Application No.: 09/728,553
Examiner: A Lewis

White discloses an apparatus for use in tracheal intubation of a patient, said apparatus comprising a tracheal tube (18) which is movable along an insertion path into a patient's trachea, an emitter (20) connected with a leading end portion of said tracheal tube, said emitter being effective to provide an output during movement of said tracheal tube along the insertion path, and a plurality of detectors in an array adjacent to the patient's Adam's apple (Col. 9, lines 17-12), each detector of said plurality of detectors being responsive to the output from said emitter and means connected with said plurality of detectors for determining the position of the leading end portion of said tracheal tube along the insertion path as a function of output from said plurality of detectors during movement of said tracheal tube along the insertion path (fig. 11, 14-18).

For the reasons set forth below, Applicant respectfully submits that claim 208 is not taught or suggested by White.

White discloses that although the magnetic flux device uses a lamp as an indicator, it will be apparent to those skilled in the art that a sound generating device (such as a buzzer) could also be used. (Col. 5, lns. 16-20). As such, White discloses a detector that emits a light or audible sound when exposed to a magnetic field.

Claim 208 recites an apparatus for use in tracheal intubation of a patient. The apparatus includes a tracheal tube that is movable along an insertion path into a patient's trachea. An emitter is connected with a leading end portion of the tracheal tube, with the emitter being effective to provide an output during movement of said tracheal tube along the insertion path. A plurality of detectors is also included, disposed in an array adjacent to the patient's Adam's apple, where each detector of the plurality of detectors is responsive to the output from said emitter. Further included is a micro processing unit connected with the plurality of detectors for indicating the position of the leading end portion of the tracheal tube along the insertion path as a function of outputs from the plurality of detectors during movement of the tracheal tube along the insertion path.

Applicant submits that the invention as claimed in claim 208 is not disclosed in White. Specifically, White discloses a detector that emits a light or sound when exposed to a magnetic field. As such, White does not disclose all of the elements of amended claim 208.

Applicant(s): Bonutti, Peter M
Application No.: 09/728,553
Examiner: A Lewis

In light of the foregoing, amended independent claim 208 is respectfully submitted to be patentable over White. As claim 211 depends from amended claim 208 and necessarily include all the elements of its base claim, Applicant hereby respectfully requests reconsideration and withdrawal of the §102(b) rejections.

35 U.S.C. § 102(b)-Berci

Claim 199 was rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,846,153 to Berci ("Berci"). The Examiner asserted:

Berci discloses an apparatus for use in tracheal intubation, said apparatus comprising a tracheal tube (fig. 3,4), sensor means (22) connected with said tracheal tube for determining the position of a leading end portion of said tracheal tube during movement of said tracheal tube along an insertion path which extends from a patient's pharynx, through the patient's larynx and into the patient's trachea (fig. 4), and steering means (55) connected with a leading end portion of said tracheal tube for applying force against the leading end portion (col. 6, lines 7-16) of said tracheal tube (fig. 3) during movement of said tracheal tube along the insertion path.

For the reasons set forth below, Applicant respectfully submits that claim 199 is not taught or suggested by Berci.

Berci relates in general to an endoscope, and more, particularly, to an endoscope having a sheath member with a controllably bendable distal or forward sheath portion and a generally rigid proximal or rearward sheath portion, which sheath member further includes an image transmitting system therethrough. (Col. 1, lns. 6- 11). At the distal end or forward tip end 14 of the sheath member 12, is a first, selectively controllable bendable section 20. (Col. 5, lns. 3-5). Bendable and flexible section 20 houses an image forming optical system 22 at its first end, and has forward and rearward end 32, 34, respectively. (Col. 5, lns. 18-19). The rearward ends 34 thereof terminates in the control housing 28 and is adapted to be operatively connected to a video system 36 for viewing the image or an object on the television monitor. (Col. 5, lns. 23-26). The image transmitting optical system 30, as configured in this preferred embodiment, permits an

Applicant(s): Bonutti, Peter M
Application No.: 09/728,553
Examiner: A Lewis

image of an object that is viewed by the image forming optical system 22 at the forward end 32 of the image transmitting optical system 30 to be transmitted therethrough to the rearward end 34 thereof, to be converted at the proximal end portion 16 of the sheath member 12 for transmission to and viewing on the television monitor. (Col. 5, lns. 27-34).

As such, Berci discloses a sheath member having an optical system on its distal end. The optical system is connected to a video system for viewing the image.

Claim 199 includes the element "sensor means connected with said tracheal tube for determining the position of a leading end portion of said tracheal tube during movement of said tracheal tube along an insertion path which extends from a patient's pharynx."

The present invention discloses that the sensor assembly 420 includes an emitter portion 424 which provides an output and a detector portion 426 which responds to the output from the emitter. (Page 67, lns. 7-11). The emitter portion 424 is positioned on an outer surface of the neck of the patient adjacent to the Adam's apple. (Page 67, lns. 12-14). The detector portion 426 is connected with the lead end portion 52c of the of a guide rod 50c. (Page 67, lns. 14-15). However it should be understood that the emitter portion 424 could be connected with the guide rod 50c and the detector portion 426 positioned adjacent to the Adam's apple 34c of the patient. (page 67, lns. 16-19).

The tracheal tube may have a second detector portion. (Page 74, lns. 6-7). By providing the tracheal tube with a second detector portion, and by maintaining the emitter portion 424 in position relative to the Adam's apple 34c, the output from the second detector portion may be utilized to locate the leading end portion of the tracheal tub. (Page 74, lns. 13-17).

In an alternative embodiment the tracheal tube can be provided with an emitter portion. (Page 83, lns 5-6). The emitter portion on the tracheal tube would interact with a detector portion position in position relative to the Adam's apple of the patient. As such, the present invention discloses a sensor means include an emitter portion and a detector portioned which are used to determine the position of the tracheal tube.

Applicant submits that the invention as claimed in claim 199 is not disclosed in Berci. Specifically, Berci discloses a sheath member having an optical system on its distal end, the

Applicant(s): Bonutti, Peter M
Application No.: 09/728,553
Examiner: A Lewis

optical system is connected to a video system for viewing the image. As such, Berci does not disclose all of the elements of claim 199.

In light of the foregoing, independent claim 199 is respectfully submitted to be patentable over Berci. Applicant hereby respectfully requests reconsideration and withdrawal of the §102(b) rejection.

35 U.S.C. § 102(h)-Hawk

Claim 225-230, 233, and 234 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,727,872 to Hawk ("Hawk"). The Examiner asserted:

Hawk discloses a method of treating a patient, said method comprising the steps of locating a positioning apparatus (10, 60) relative to a portion of the patient's body (i.e. mouth/throat) by engaging the patient's body with the positioning apparatus, determining a position to which a elongated member (i.e. endotracheal tube) is to be moved relative to the positioning apparatus (col. 4, lines 59-61), moving the elongated member into the patient's body while the positioning apparatus is in engagement with the patient's body (col. 4 lines 66-67), interrupting movement of the elongated member into the patient's body when the elongated member has moved to the previously determined position relative to the positioning apparatus (i.e. after positioning the endotracheal tube within the patient's trachea), and performing a procedure (e.g. ventilating the patient via the endotracheal tube) in the patient's body while the elongated member is in the previously determined position relative to the patient's body.

For the reasons set forth below, Applicant respectfully submits that claim 225 is not taught or suggested by Hawk.

Hawk discloses an endotracheal cannula and a system for supporting the cannula during intubation of a patient. (Col. 1, lns. 62-64). The system for supporting the cannula includes a bridge assembly spanning an operating table supporting the cannula above a patient. (Col. 2, lns. 3-5). A curved endotracheal cannula 10 is illustrated suspended from a support system 11 in the mouth and throat of a patient. (Col. 2, lns. 56-58 and FIG. 1).

As such, Hawk discloses a support system attached to the operating table (See FIG. 1),

Applicant(s): Bonutti, Peter M
Application No.: 09/728,553
Examiner: A Lewis

which supports a cannula. The cannula is positioned in the mouth and throat of the patient.

Claim 225 recites a method of treating a patient. The method includes the step of locating a positioning apparatus relative to a portion of the patient's body by engaging the patient's body with the positioning apparatus, wherein a portion of the positioning apparatus is positioned adjacent to an Adam's apple of the patient.

Applicant submits that the invention as claimed in claim 225 is not disclosed in Hawk. Specifically, Hawk discloses an endotracheal cannula and a system for supporting the cannula during intubation of a patient. The support system is disclosed as being attached to the operating table (See FIG. 1). The cannula, which is supported by the support system, is positioned in the mouth and throat of the patient. Neither the support system nor the cannula is positioned adjacent to the Adam's apple. As such, Hawk does not disclose all of the elements of claim 225.

In light of the foregoing, amended independent claim 225 is respectfully submitted to be patentable over Hawk. As claims 226-230 and 233-241 depend from amended claim 225 and necessarily include all the elements of their base claim, Applicant hereby respectfully requests reconsideration and withdrawal of the §102(b) rejections.

35 U.S.C. § 103(a)- White

Claim 206 was rejected under 35 U.S.C. §103(a) as being unpatentable over White.

Claim 206 depends from independent claim 202, including all of the elements thereof.

As noted above, Applicant submits that claim 202 is patentable over White. Accordingly, Applicant submits that claim 206 is also patentable over White and hereby respectfully requests reconsideration and withdrawal of the §103(a) rejection

Conclusion

For all of the above reasons, the claim rejections are believed to have been overcome, placing all pending claims in condition for allowance, and reconsideration and allowance thereof is respectfully requested.

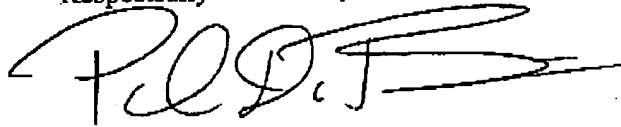
The Examiner is encouraged to telephone the undersigned to discuss any matter that

Applicant(s): Bonutti, Peter M
Application No.: 09/728,553
Examiner: A Lewis

would expedite allowance of the present application.

Please charge any required fee (or credit any overpayments of fees) to the Deposit
Account of the undersigned, Account No. 500601 (Docket No. 780-A02-033).

Respectfully submitted,



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